Role of fine-needle aspiration biopsy and frozen-section evaluation in the surgical management of thyroid nodules


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of intraoperative frozen section (FS) and fine-needle aspiration biopsy (FNAB) for the evaluation of thyroid nodules that require surgical treatment.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who presented with a multinodular goitre or a thyroid nodule. All had one or more palpable thyroid nodules with a diameter greater than 1 cm. All were euthyroid. Patients with impaired thyroid function were excluded.

Setting
The setting was secondary care. The economic study was conducted at the University of Turin, S. Luigi Hospital, Orbassano, Turin, Italy.

Dates to which data relate
The effectiveness and resource use data were gathered between January 1995 and December 2000. The price year was not reported.

Source of effectiveness data
The effectiveness evidence came from a single study.

Link between effectiveness and cost data
The costing was performed retrospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations do not appear have been conducted. A sample of 206 consecutive patients who were admitted to the study hospital and underwent surgery there, during the period January 1995 to December 2000, was enrolled in the study and underwent both FNAB and intraoperative FS. There were 173 women and 33 men. The mean age was 49 (+/- 14 years) (median age: 49; range: 14 - 89).
Study design
The study was based on the analysis of a retrospective cross-sectional diagnostic study, where FNAB, FS and the reference test were performed on all patients. The study was conducted in a single centre. The patients were followed until the diagnosis was made. The reference test was definitive histological analysis of between 4 and 10 serial sections. The pathologist who reported the FS was blinded to the results of the other test. The results of FNAB were classified as benign, malignant or suspicious. The indications for operation included a cytological diagnosis of malignancy or of suspected malignancy, so suspected malignancies were grouped together with malignancies in the analysis. The results of FS were classified as benign, malignant or deferred (inconclusive). For statistical analysis, the inconclusive results were classified as false negatives.

Analysis of effectiveness
All patients included in the study sample were accounted for in the analysis. The health outcomes used in the analysis were the sensitivity, specificity, overall accuracy, positive predictive value (PPV) and negative predictive value (NPV).

Effectiveness results
For FNAB, of the 206 patients, 79 were benign, 113 suspicious and 14 malignant.

For FS, of the 206 patients, 165 were benign, 8 deferred and 33 malignant.

The sensitivity values were 88% for FNAB and 80% for FS.

The specificity values were 45% for FNAB and 99% for FS.

The accuracy values were 53% for FNAB and 96% for FS.

The PPV was 28% for FNAB and 97% for FS.

The NPV was 94% for FNAB and 95% for FS.

Clinical conclusions
The main result of the effectiveness analysis was that FNAB was associated with higher sensitivity than FS. However, FS had much higher specificity.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis was therefore conducted.

Direct costs
The cost/resource boundary was that of the third-party payer. The health service costs included in the economic evaluation were thyroidectomy, FS and FNAB. Discounting was not relevant since the costs were incurred over a short period of time. The unit costs were reported separately from the quantities of resources used. The costs were estimated on the basis of regional refunding fees to the study hospital. Resource consumption was obtained from the actual consumption of the patients included in the effectiveness study from January 1995 to December 2000. The hypothetical costs of performing either no FS or FS in all patients were calculated. No price year was reported.

Statistical analysis of costs
The costs were treated deterministically.
Indirect Costs
The indirect costs were not included.

Currency
Euros.

Sensitivity analysis
Sensitivity analyses were not conducted.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total cost of performing FS in all 206 patients was Euro 16,686.

The routine use of FS led to eight, second operations at a total cost of Euro 16,520.

Surgical decisions based on FNAB would result in total costs of Euro 53,690. Thus, the routine use of FS led to savings of Euro 20,484, which were determined by a lower number of operations.

Synthesis of costs and benefits
Not relevant as a cost-consequences analysis was conducted.

Authors' conclusions
Frozen section (FS) had a higher accuracy value and lower costs in comparison with fine-needle aspiration biopsy (FNAB). Thus, it represented an important diagnostic tool in the surgical management of thyroid nodules.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. FNAB represented a widely used test to select patients requiring surgery for thyroid nodules, while FS represented the routine approach in the authors' unit. You should decide whether they are widely used diagnostic techniques in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness analysis used a retrospective cross-sectional diagnostic study. Although the study was retrospective, the diagnostic protocol that prevailed in the centre seemed to be of a high standard. Overall, the internal validity should be quite high. Some patient characteristics were reported, which helps enhance the applicability of the results. However, there were no sample size calculations and we cannot be sure of how representative the patient spectrum was. Work-up bias should be absent as each patient underwent both tests and the reference test. Review bias should be low as the pathologist who conducted the test was blinded to the result of the FNAB test when doing the FS test. The precision of the results, however, was not analysed.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study.
Validity of estimate of costs
The perspective adopted in the study was reported and only the categories of costs strictly relevant to the study interventions were included in the analysis. The unit costs were reported separately from the quantities of resources. However, no price year was reported, thus making reflation exercises in other settings difficult. Further, the cost estimates were specific to the study setting. Uncertainty was not evaluated through statistical tests.

Other issues
The authors made some comparisons of their findings with those from other studies and found their results to be similar to those reported. However, the authors did not address the issue of the generalisability of the study results to other settings and did not perform sensitivity analyses. Thus, the external validity of the analysis was low. The study referred to patients requiring thyroidectomy and this was reflected in the conclusions of the analysis. The results were adequately reported.

Implications of the study
The study suggests that FS and FNAB should form part of a complementary approach, with FNAB used primarily for the selection of patients for surgery (high sensitivity) and FS employed to plan the extent of surgery (high specificity). The authors stated "FS can be avoided when the FNAB result is consistent with malignancy, but could be of value when the FNAB result is reported as suspicious, inadequate or even benign".

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